

DANIEL HUBERT, individually and on behalf of all others similarly situated,	:	Civil Action No. 2:15-cv-01391-MRH
	:	
	:	
Plaintiff,	:	
	:	Oral Argument Requested
v.	:	
	:	This Document Relates
GENERAL NUTRITION CORPORATION,	:	All Actions
	:	
Defendant.	:	
	:	
(In re: GNC Picamilon/BMPEA Litigation)	:	

Plaintiffs, on behalf of themselves and members of the putative class, submit the following opposition to Defendant General Nutrition Corporation’s (“Defendant’s”) Request for Judicial Notice in Support of its Motion to Dismiss Second Amended Consolidated Complaint (“Request for Judicial Notice”) (ECF No. 86-5).

Through the Request for Judicial Notice, Defendant improperly seeks to have this Court decide disputed issues of fact in this case on its Motion to Dismiss Second Amended Consolidated Complaint (“Motion to Dismiss” or “Mot.”). Defendant asks this Court to take judicial notice of eleven documents: (1) a U.S. Food and Drug Administration (“FDA”) warning letter dated April 22, 2015 to Hi-Tech Pharmaceuticals, Inc. (attached as Exhibit C to the Declaration of Stephen Cherry (“Cherry Decl.”), ECF No. 89-1 and 86-2 at 1); (2) a Department of Health and Human Services (“DHHS”) Certificate of Free Sale dated April 15, 2015 and signed by Dr. Cara Welch (the “Certificate”) (Cherry Decl., Ex. D, ECF No. 86-2 at 16); (3) the

Declaration of Dr. Cara Welch filed in *State of Oregon v. General Nutrition Corporation*, Case No. 15CV28591, in the Circuit Court of the State of Oregon for the County of Multnomah (the “Welch Declaration” filed in the “Oregon Action”) (Cherry Decl., Ex. E, ECF No. 86-2 at 21); (4) an FDA warning letter dated November 30, 2015 to SDC Nutrition, Inc. (Cherry Decl., Ex. G, ECF No. 86-2 at 27); (5) an FDA warning letter dated March 7, 2016 to Nubreed Nutrition, Inc. (Cherry Decl., Ex. H, ECF No. 86-2 at 30); (6) the October 22, 2015 complaint filed against Defendant in the Oregon Action (Cherry Decl., Ex. I, ECF No. 86-2 at 34); and (7) five documents available on the FDA’s website including four informational documents (attached as Exhibits J-K and M-N to the Declaration of Amy B. Alderfer (“Alderfer Decl.”), ECF No. 86-3 and 86-4) and Chapter 4-1-1 of the July 2012 “Regulatory Procedures Manual” (the “Manual”) (Alderfer Decl., Ex. L, ECF No. 86-4 at 1).

II. ARGUMENT

Defendant’s Request for Judicial Notice suffers from two overarching defects. First, judicial notice is only appropriate for facts that are not in dispute by the parties. Second, Defendant improperly seeks judicial notice of documents that were not integral to, or relied upon by Plaintiffs in, the Second Amended Consolidated Class Action Complaint (“Complaint”). At bottom, Defendant is attempting to improperly use some of these documents to put facts before this Court to support its Motion to Dismiss. Defendant’s attempt to persuade the Court to improperly decide disputed issues of fact in its favor on this pleading motion should be denied.

A. The Parties Dispute the Accuracy or Interpretation of Certain of the Documents

Defendant bases its request for judicial notice on Fed. R. Evid. 201(b), which provides that a court “may judicially notice a fact that is *not subject to reasonable dispute* because it: (1) is *generally known* within the trial court’s territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy *cannot reasonably be questioned*.” (Emphasis

added).¹ These stringent requirements exist because “[f]or all practical purposes, judicially noticing a fact is tantamount to directing a verdict against a party as to the noticed fact.” *LaSalle Nat’l Bank v. First Conn. Holding Group, L.L.C.* XXIII, 287 F.3d 279, 290 (3d Cir. 2002). Here, Defendant seeks judicial notice of facts that are highly disputed by Plaintiffs, and therefore Defendant’s interpretation of such facts in support of its Motion to Dismiss should not be judicially noticed.

While Plaintiffs accept the *existence* of the documents referenced in Defendant’s Request, Plaintiffs do not concede the accuracy of much of the information contained in those documents and/or their significance to this case. Courts typically reject attempts to conflate these two concepts when the party is improperly using the judicial notice vehicle to decide disputed issues of fact in its own favor. *See, e.g., United States v. Onyenso*, No.12-CR-602 (CCC), 2015 U.S. Dist. LEXIS 77582, at *21 (D.N.J. June 16, 2015) (court declined to take judicial notice of regulation because its application to defendant was unclear and was “the subject of vigorous dispute between the parties.”); *Trevino v. Merscorp, Inc.*, 583 F. Supp. 2d 521, 527 (D. Del. 2008) (“In general, documents may not be judicially noticed for the truth of the matters stated in them.”) (quoting Jack B. Weinstein & Margaret A. Berger, Weinstein’s Federal Evidence § 201.12[3] (2d ed. 2008)). Because the parties dispute the contents of certain documents and/or their application to the facts of this case, they should not be judicially noticed.²

B. Defendant Inappropriately Requests Judicial Notice of Documents Extraneous to the Pleadings

Defendant’s Request for Judicial Notice wrongly asks this Court to take notice of documents outside of the Complaint. In ruling on a motion to dismiss, a district court generally

¹ Defendant does not argue that judicial notice is appropriate because any of the documents or facts at issue are “generally known within the trial court’s territorial jurisdiction.”

² In responding to this point in its reply in support of its first request for judicial notice, *see* ECF No. 63, Defendant gave up the game by conceding that “GNC is not *necessarily* attempting to introduce the documents for the statements asserted herein.” *Id.* at 2 (emphasis added).

may not consider matters or documents extraneous to the pleadings. *See Angelastro v. Prudential Bache Securities*, 764 F.2d 939, 944 (3d Cir. 1985). An exception to the general rule is that a “document integral to or explicitly relied upon in the complaint” may be considered. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotations omitted); *see also In re Donald J. Trump Casino Securities Litigation-Taj Mahal Litigation*, 7 F.3d 357, 368 n.9 (3d Cir. 1993) (quoting *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (“a court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff’s claims are based on the document.”)). Defendant seeks judicial notice of documents and facts that are not integral to, or even discussed in, the Complaint.

Defendant largely seeks judicial notice of these documents in an attempt to contradict facts properly and plausibly alleged in the Complaint. But Plaintiffs’ allegations of fact are to be taken as true at this stage of the litigation. *See Westmoreland Advanced Materials, Inc. v. Allied Mineral Prods.*, Nos. 16cv0263, 16cv604, 2016 U.S. Dist. LEXIS 76801, at *5 (W.D. Pa. June 13, 2016). Therefore, Defendant’s request that the Court take judicial notice of these documents is improper to the extent that Defendant uses the documents to contradict Plaintiffs’ allegations with its own interpretation of such documents. Accordingly, even if the existence of these documents is not in dispute, Defendant cannot use the mechanism of judicial notice to decide disputed issues of fact in Defendant’s favor on this Motion to Dismiss.³

³ Defendant notably does not seek judicial notice of all documents it presents. For example, Defendant does not seek judicial notice of Exhibit F to the Cherry Declaration, purported to be a September 28, 2015 email from Oregon Senior Assistant Attorney General David Hart to Defendant’s counsel in Oregon (but not to Cherry). Nor could it, for two reasons. First, Cherry has no personal knowledge of this document. Second, the email was not mentioned or referred to in Plaintiffs’ Complaint. Accordingly any reference to this email should be stricken.

Defendant also fails to seek judicial notice of Exhibit B to the Cherry Declaration, an April 9, 2015 article from the New York Times titled “Retailers to Stop Sales of Controversial Supplements.” Judicial notice cannot be taken of this article because the Complaint does not mention or rely upon it. Although Defendant does not appear to cite to this article in its Motion, any reference to this article here or in Defendant’s reply brief should, likewise, be stricken.

C. The Following Documents Convey Facts in Dispute and/or Exist Wholly Apart from the Complaint

While the foregoing principles apply generally to the documents at issue, Plaintiffs individually address why certain of these documents should not be judicially noticed.

1. April 22, 2015 FDA Warning Letter to Hi-Tech Pharmaceuticals, Inc., the November 30, 2015 FDA Warning Letter to SDC Nutrition, Inc. and the March 7, 2016 FDA Warning Letter to Nubreed Nutrition, Inc. (Cherry Decl., Exs. C, G, I)

Plaintiffs do not dispute the existence of these documents. However, Defendant seeks judicial notice of these warning letters to definitively establish its interpretation of the warning letters. Defendant states that the warning letters are merely “informal and advisory” and in no way “pronounce[the Ingredients] to be unlawful.” *See* Mot. at 20-21. On the other hand, Plaintiffs contend that the warning letters support allegations that the Ingredients were deemed illegal. Because Plaintiffs strongly dispute Defendant’s interpretation of the warning letters, judicial notice should be denied.

2. April 15, 2015 DHHS Certificate of Free Sale (Cherry Decl., Ex. D)

Plaintiffs object to the Court taking judicial notice of the existence of the Certificate as it is outside the scope of Plaintiffs’ Complaint and not relied upon for their claims.⁴ Plaintiffs further dispute Defendant’s improper purpose for seeking judicial notice of the Certificate, namely to support Defendant’s assertion that the Certificate’s issuance is “inconsistent” with the Welch Declaration. Mot. at 6. In other words, Defendant seeks a ruling from the Court that the Certificate contradicts the Welch Declaration’s determination that picamilon is not a dietary ingredient under the Food, Drug and Cosmetic Act (“FDCA”). *See* Mot. at 6 (Certificate “*in essence* announce[s] to the world that the subject products are freely (and lawfully) available for sale in the U.S. . . . Thus, as of April 15, 2015, the FDA’s public position was that picamilon

⁴ In its reply in support of its first request for judicial notice, *see* ECF No. 63, Defendant conceded that the Certificate is only tangentially related to the allegations of the Complaint. *See id.* at 2 (“the entire FAC is replete with allegations regarding the legality of the sale of the products, which *directly relates* to the Certificate of Free Sale”) (emphasis added). Such an attenuated connection to the Complaint is insufficient for judicial notice.

was (*at least impliedly*) a lawful dietary ingredient.”) (Emphasis added). Accordingly there is a clear dispute over the “significance of the contents” of the Certificate, and therefore it is not subject to judicial notice.

3. FDA Webpage Entitled “Export Certificates” (Alderfer Decl., Ex. J)

Plaintiffs object to the Court taking judicial notice of this webpage because it exists outside the scope of the Complaint and Plaintiffs do not rely upon it for their claims. Plaintiffs also dispute Defendant’s interpretation of the webpage’s content. Defendant maintains that the FDA’s issuance of Export Certificates for the products at issue establishes that the FDA agrees with the product representations and that, therefore, Defendant is immunized from civil liability as a result. *See* Mot. at 7 (“The Certificates *in essence* announce to the world that the subject products are freely (and lawfully) available for sale in the U.S.”) (emphasis added). Plaintiffs, on the other hand, maintain that the FDA takes a contrary position in both its letters and declarations in the Oregon Action. Accordingly, there is a clear dispute over the “significance of the contents” of the statements on this webpage that precludes it from being judicially noticed.

4. Chapter 4-1-1 of Regulatory Practices Manual Dated July 2012 (Alderfer Decl., Ex. L)

Plaintiffs object to the Court taking judicial notice of the existence of this chapter of the Manual because it exists outside the scope of the Complaint and Plaintiffs do not rely upon it for their claims. The significance of this document is also subject to dispute, as Plaintiffs do not agree with Defendant’s attempt to defang the import of the warning letters by interpreting the Manual as providing that “warning letters simply communicate the agency’s position on a matter without committing the FDA to an enforcement action.” Mot. at 19. Accordingly, taking judicial notice of this document would be inappropriate.

5. FDA Webpage Entitled “Letter of Guaranty” (Alderfer Decl., Ex. M)

Plaintiffs object to the Court taking judicial notice of the existence of this webpage because it exists outside the scope of the Complaint and Plaintiffs do not rely upon it for their claims. Plaintiffs also dispute Defendant’s apparent proffered legal conclusion that, according to

this webpage, a “Letter of Guaranty” insulates sellers of products from civil liability. *See* Mot. at 22. For all of the reasons discussed at length in Plaintiffs’ concurrently filed Opposition to Defendant’s Motion to Dismiss, *see id.*, Section IV.D, a Letter of Guaranty at most exempts innocent retailers from criminal prosecution under the FDCA and does not immunize its recipient from civil liability or other consequences of selling misbranded food. Accordingly, this document also cannot be judicially noticed.

6. FDA Webpage Entitled “New Dietary Ingredients in Dietary Supplements – Background for Industry” (Alderfer Decl., Ex. N)

Plaintiffs object to the Court taking judicial notice of the existence of this webpage because it exists outside the scope of the Complaint and Plaintiffs do not rely upon it for their claims. Plaintiffs also dispute the rationale for Defendant’s improper submission of this document in its defense on a motion to dismiss, that Defendant is absolved from Plaintiffs’ allegations because it is neither a “manufacturer” or “distributor” of the Products at issue. But as explained in Plaintiffs’ Opposition, this is irrelevant to Plaintiffs’ claims, a fact supported by this very document which provides that “[r]egardless of whether you are required to submit a premarket notification, you are responsible for evaluating the safety of dietary ingredients you use, and you must ensure that dietary supplements you sell or distribute are not adulterated.” Alderfer Decl., Ex. N at 3. Accordingly, this document cannot be judicially noticed.

III. CONCLUSION

For the reasons discussed herein, Plaintiffs respectfully request that this Court deny Defendant’s Request for Judicial Notice of the documents discussed herein.

Dated: November 14, 2017

Respectfully submitted,

/s/ Shanon J. Carson

Shanon J. Carson, Esquire (Pa. ID No. 85957)

Arthur Stock, Esquire (Pa. ID No. 64336)

Berger & Montague, P.C.

1622 Locust Street

Philadelphia, PA 19103

Telephone: (215)875-4656

Facsimile: (215) 875-4604

scarson@bm.net

astock@bm.net

Gary E. Mason, Esquire

Jennifer S. Goldstein, Esquire

Whitfield Bryson & Mason, LLP

5101 Wisconsin Ave., NW, Ste 305

Washington, DC 20036

Telephone: (202) 429-2290

Facsimile: (202) 429-2294

gmason@wbmlp.com

jgoldstein@wbmlp.com

Co-Lead Counsel

D. Aaron Rihn, Esquire

Robert Peirce & Associates, P.C.

707 Grant Street

Suite 2500

Pittsburgh, PA 15219-1918

Telephone: (412) 281-7229

Facsimile: (412) 281-4229

arihn@peircelaw.com

Gregory F. Coleman, Esquire
Mark E. Silvey, Esquire
Lisa A. White, Esquire
Greg Coleman Law, P.C.
First Tennessee Plaza
800 S. Gay Street
Suite 1100
Knoxville, TN 37929
Telephone: (865) 247-0090
Facsimile: (865) 522-0049
greg@gregcoleman.law
mark@gregcolemanlaw.com
lisa@gregcolemanlaw.com

John Yanchunis, Esquire
Marcio Valladares, Esquire
Patrick A. Barthle II, Esquire
Rachel L. Soffin, Esquire
Morgan & Morgan
Complex Litigation Group
201 North Franklin Street
7th Floor
Tampa, Florida 33602
Telephone: (813) 223-5505
Facsimile: (813) 223-5402
jyanchunis@forthepeople.com
mvalladares@forthepeople.com
pbarthle@forthepeople.com
rsoffin@forthepeople.com

Janine Pollack, Esquire
Michael Liskow, Esquire
Wolf Haldenstein Adler Freeman & Herz LLP
70 Madison Avenue
New York, New York 10016
Telephone: (212) 545-4600
Facsimile: (212) 545-4653
pollack@whafh.com
liskow@whafh.com

Theodore B. Bell, Esquire
Carl Malmstrom, Esquire
Wolf Haldenstein Adler Freeman & Herz LLP
One South Dearborn St.
Suite 2122
Chicago, IL 60603
Telephone: (312) 984-0000
Facsimile: (312) 212-4401
tbell@whafh.com
malmstrom@whafh.com

Robert K. Shelquist, Esquire
Craig S. Davis, Esquire
Rebecca A. Peterson, Esquire
Lockridge Grindal Nauen P.L.L.P.
100 Washington Avenue South
Suite 2200
Minneapolis, MN 55401
Telephone: (612) 339-6900
Facsimile: (612) 339-0981
rkshelquist@locklaw.com
cdavis@locklaw.com
rapeterson@locklaw.com

Eric H. Gibbs, Esquire
Andre M. Mura, Esquire
Caroline Corbitt, Esquire
Girard Gibbs LLP
601 California Street, 14th Floor
San Francisco, CA 94108
Phone: (415) 981-4800
Facsimile: (415) 981-4846
ehg@girardgibbs.com
amm@girardgibbs.com
ccc@girardgibbs.com

Attorneys for Plaintiffs

DANIEL HUBERT, individually and on behalf of all others similarly situated,	:	Civil Action No. 2:15-cv-01391-MRH
	:	
	:	
Plaintiff,	:	
	:	
v.	:	Oral Argument Requested
	:	
	:	
GENERAL NUTRITION CORPORATION,	:	This Document Relates
	:	All Actions
	:	
Defendant.	:	
	:	
	:	
(In re: GNC Picamilon/BMPEA Litigation)	:	

By: /s/ Shanon J. Carson
Shanon J. Carson
Pa. I.D. No. 85957
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103